

DEPARTMENT OF FINANCE BILL ANALYSIS

AMENDMENT DATE: July 16, 2008
POSITION: Oppose
SPONSOR: Board of Pharmacy

BILL NUMBER: SB 1307
AUTHOR: M. Ridley-Thomas
RELATED BILLS: SB 1270 (2008)
SB 1307 (2004)
SB 1476 (2006)

BILL SUMMARY: Pharmacy - Pedigree Extension

This bill would require manufacturers, wholesalers, and distributors of pharmaceuticals, including pharmacies, between, January 1, 2011 and December 31, 2015, to take specific steps to maintain an electronic record of transactions that result in change of ownership of dangerous drugs with full implementation by July 1, 2016.

FISCAL SUMMARY

This bill affects any pharmacy that dispenses pharmaceuticals, including state pharmacies such as those operated by the University of California, Veterans Homes, and California Department of Corrections and Rehabilitation. Therefore, the state would incur potentially significant costs to maintain an electronic record of transactions. It is estimated that these state pharmacies as well as each private and local government pharmacy would incur costs ranging from \$50,000 to \$100,000 per location to purchase equipment necessary to implement the provisions of this bill.

While this bill will phase in the implementation costs, it is estimated that manufacturers and wholesalers subject to the provisions of this bill would incur expenses in the hundreds of millions. To the extent that the federal government adopts pedigree regulations or the technology has an opportunity to become more fully developed, the actual costs may be reduced. Any increase in costs will also affect the cost of prescription drugs paid by state agencies. Based on expenditures of \$220 million for drug purchases by the Department of General Services, every 0.1 percent increase will result in an increase to the state of \$220,000 primarily affecting departments that are either entirely funded by the General Fund or have a majority of their funding from General Fund sources.

While this bill imposes additional duties for tracking and implementing the pedigree requirements over a longer period of time, we estimate that costs for the Board of Pharmacy (Board) would be minor and absorbable (up to \$45,000) as they have been working on them since 2005. In addition, the Board estimates costs of \$239,000 beginning in 2010-11 to track wholesalers that use the alternate process.

Any local government costs resulting from the mandate in this bill would not be state-reimbursable because the mandate is not unique to local government.

COMMENTS

Finance is opposed to this bill due to the fiscal impact to state entities affected by this bill which could require significant General Fund expenditures as the implementation progresses. In addition, this bill will increase costs to manufactures, wholesalers, and distributors of pharmaceuticals which will likely be passed on to consumers at a time when health care costs are increasing throughout the system. Finally, this bill is premature as the federal government has been working to implement similar requirements. While this bill requires the reconciliation of state standards with national standards, it would be more prudent to delay additional expenditure of state resources until the national standards have been adopted. This bill would provide more time to implement pedigree requirements that are intended to address the possible threat of pharmaceutical counterfeiting and misbranding. Delaying implementation of pedigree requirements may benefit the state as it would allow:

- The federal government to finish implementation of their pedigree regulations (anticipated to be completed by 2010) so the state can implement corresponding standards.
The task force that would be established by SB 1270 (Cedillo) to develop standards that provide an inclusive process for all interested parties.

Analyst/Principal Date Program Budget Manager Date
(0240) K. Shelton Todd Jerue

Department Deputy Director Date

Governor's Office: By: Date: Position Approved
Position Disapproved

BILL ANALYSIS Form DF-43 (Rev 03/95 Buff)

**BILL ANALYSIS/ENROLLED BILL REPORT--(CONTINUED)**  
**AUTHOR** **AMENDMENT DATE**

M. Ridley-Thomas

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- The technology necessary to implement pedigree requirements to evolve.

Existing law:

- As of January 1, 2009, would prohibit selling, trading, or transferring a pharmaceutical without providing a pedigree.
- Defines a pedigree as a record in electronic form containing the history of all transactions that result in a change of ownership of prescription drugs from the manufacturer to the pharmacy.
- Permits extension of the pedigree requirement to January 1, 2011.

This bill would:

- Require manufacturers to have 20 percent of their dangerous drugs and meet the serialized electronic pedigree requirements by January 1, 2011, an additional 30 percent by January 1, 2013, and the remaining 50 percent by January 1, 2016.
- Specify that manufactures shall not be required to meet these requirements for generic drugs anytime before January 1, 2015.
- Prohibits, after January 1 2015, a wholesaler from acquiring a dangerous drug without receiving a pedigree.
- Prohibits, after July 1, 2015, a pharmacy from acquiring, selling, trading, or transferring a dangerous drug.
- Provide exemptions from the pedigree requirements for specified drugs.
- Allows for the inference of the contents of a case, pallet, or other aggregate of individual units, from a unique identifier without individually validating each unit, under specified conditions.
- Require the Board to implement specified federal pedigree identification standards if such standards are developed by the federal government and establish an effective date that allows for a reasonable implementation time frame.
- Require the Board to reconcile the national standards with the requirements outlined in California's law within 90 days of enactment of the federal law.
- Make various conforming adjustments.

We note that pedigree requirements were initially set to be made operative on January 1, 2007 per Chapter 857, Statutes of 2004, delayed to January 1, 2009 by Chapter 658, Statutes of 2006, and would be further delayed by this bill as outlined above.

Code/Department Agency or Revenue Type	SO	(Fiscal Impact by Fiscal Year)							Fund Code
	LA	(Dollars in Thousands)							
	CO	PROP							
	RV	98	FC	2008-2009	FC	2009-2010	FC	2010-2011	
1110/ConAfr-ReqBd	SO	No	A	\$45	A	\$45	A	\$269	0767
9990/Var Depts	SO	No		----- See Fiscal Analysis -----					0001
<u>Fund Code</u>	<u>Title</u>								
0001	General Fund								
0767	Pharmacy Board Contingent Fund								